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(72) FRAZER, Hugh, CA

(71) FRAZER, Hugh, CA

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(54) APPAREIL INTRA-ORAL FAIT SUR MESURE PERMETTANT DE REDUIRE LES CONTRACTIONS MUSCULAIRES (54) A CUSTOM, INTRA-ORAL, MUSCLE-CONTRACTION REDUCTION APPARATUS

> 14 15 10 13 11 18

(57) Appareil intra-oral en deux parties fait sur mesure qui prévient la contraction intense des muscles releveurs du mandibule en déclenchant le réflexe d'ouverture de la mâchoire. La partie supérieure de l'appareil s'ajuste sur les six dents antérieures maxillaires afin de former une plate-forme lisse et plane. Elle suit antérieurement la courbe des dents avec une bordure postérieure plane et s'étend depuis une canine jusqu'à la canine de l'autre côté du palais. La partie inférieure de l'appareil s'ajuste sur les quatre incisives mandibulaires et comprend un petit dôme sur l'axe longitudinal des deux incisives centrales dans la partie médiane. Lorsque les dents

(57) A custom, intra-oral apparatus in two parts which prevents intense contraction of the elevator muscles of the mandible by triggering the Jaw Opening Reflex. The upper part of the apparatus fits over the maxillary six anterior teeth forming a smooth, flat platform, anteriorly following the curvature of the teeth with a flat posterior border, running from the cuspid to the cuspid across the palate. The lower part of the apparatus fits over the four mandibular incisors and has a small dome located over the longitudinal axis of the two central incisors at the midline. When the upper and lower teeth are brought together, the dome of the lower part of the apparatus

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supérieures et inférieures entrent en contact, le dôme de la partie inférieure de l'appareil s'engage avec la plateforme plane de la partie supérieure, dirigeant ainsi la force exercée par les muscles vers le bas de l'axe long des incisives inférieures. Cette action déclenche le réflexe d'ouverture de la mâchoire et a pour effet de relaxer les muscles (pour éviter que les dents ne soient endommagées). Une contraction intense des muscles releveurs du mandibule durant la phase de sommeil MOR a été liée à l'étiologie complexe des céphalées chroniques, des céphalées par tension psychique et des migraines. L'appareil est conçu pour être porté durant le sommeil et, en prévenant la contraction intense des releveurs du mandibule, réduit muscles considérablement la fréquence des maux de tête. Cet appareil en deux parties remédie aux lacunes des dispositifs antérieurs constitués de seulement une partie parce qu'il évite réellement un contact entre les dents postérieures.

engages the flat platform of the upper, thus directing the force exerted by the muscles down the long axis of the lower incisors. This action triggers the Jaw Opening Reflex and causes the muscles to relax (to prevent damage to these teeth). Intense contraction of the elevator muscles of the mandible during the R.E.M. phase of sleep has been implicated in the complex etiology of chronic headache, tension-type headache and migraine headache pain. This apparatus is designed to be worn while asleep and, by preventing the intense contraction of the elevator muscles of the mandible, considerably reduces the incidence of headaches. This two part apparatus overcomes the shortcomings of previous known art consisting of only one part, because of its definitive prevention of contact of the posterior teeth.

ABSTRACT OF THE DISCLOSURE

A custom, intra-oral apparatus in two parts which prevents intense contraction of the elevator muscles of the mandible by triggering the Jaw Opening Reflex. The upper part of the apparatus fits over the maxillary six anterior teeth forming a smooth, flat platform, anteriorly following the curvature of the teeth with a flat posterior border, running from the cuspid to the cuspid across the palate. The lower part of the apparatus fits over the four mandibular incisors and has a small dome located over the longitudinal axis of the two central incisors at the midline. When the upper and lower teeth are brought together, the dome of the lower part of the apparatus engages the flat platform of the upper, thus directing the force exerted by the muscles down the long axis of the lower incisors. This action triggers the Jaw Opening Reflex and causes the muscles to relax (to prevent damage to these teeth). Intense contraction of the elévator muscles of the mandible during the R.E.M. phase of sleep has been implicated in the complex etiology of chronic headache, tension- type headache and migraine headache pain. This apparatus is designed to be worn while asleep and, by preventing the intense contraction of the elevator muscles of the mandible, considerably reduces the incidence of headaches. This two part apparatus overcomes the shortcomings of previous known art consisting of only one part, because of its definitive prevention of contact of the posterior teeth.

A CUSTOM, INTRA-ORAL, MUSCLE CONTRACTION-REDUCTION APPARATUS.

The present invention relates to chronic headaches, tension-type headaches, migraine headache pain, the pain and discomfort associated with T.M.Joint dysfunction and to the reduction of these problems by prevention of severe and intense contraction of the elevator muscles of the mandible.

To date, the approach to treating these problems has been to treat the symptoms. Physicians will usually take the drug approach and prescribe analysis and/or muscle relaxants. Other approaches include physiotherapy, chiropractic, acupuncture, homeopathy, naturopathy and craniopathy.

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The concept of addressing these problems by treating the cause by the prevention of the intense contraction of the elevator muscles of the mandible is very new and the known art is very limited.

The known art consists of single devices placed on only one dental arch. Examples of these are described in U.S. Patents # 5,085,584 and #5,513,656 dated February 4th, 1992 and May 7th, 1996 and granted to James P. Boyd. They are either custom or semi-custom made and have several drawbacks.

They very often have to adjusted many times until the stage is reached where the posterior teeth cannot be brought into contact in any excursion of the mandible. It is essential to the success of this concept, that the posterior teeth not be able to come in contact with each other or with the apparatus because, if this occurs, the intense contractions of the muscles can again take place. As soon as the posterior teeth can be clenched upon, the Jaw Opening Reflex is neutralized and its effect lost.

The design of the known art is such that a patient could move the device into a position in which pressure could be applied to a single tooth in a direction other than down the long axis of the tooth which could result in the loosening of the tooth with resultant loss of supporting bone structure.

The material with which the semi-custom devices are constructed tends to be porous, stains very easily, is easily impregnated by oral bacteria and quickly loses its clinically clean appearance.

The known art is quite difficult to adapt to situations where patients have serious malocclusions and/or deep overbites. A large antero-posterior discrepancy in the upper and lower arches (large overjet) also presents difficulties.

The apparatus in this new invention consists of two completely separate parts. The first preferably

over, and is very closely adapted to the maxillary (or upper) 6 anterior teeth (although in difficult cases where retention of the apparatus is a problem, the number of teeth incorporated into the apparatus can vary). The other part fits over and is closely adapted to, usually, the 4 lower (or mandibular) incisor teeth.

This invention embodies several ideas new to the known existing art and successfully addresses the shortcomings of the said known art.

The known existing devices have the potential to allow a clenching patient to isolate and clench on a single tooth in a direction which could result in the loosening of the tooth and the eventual loss of the bone supporting that tooth.

The design of this new apparatus completely precludes this possibility because of the smooth flat platform of the upper part of the apparatus.

The known existing devices can have a situation where it is extremely difficult to prevent the lower cuspid teeth from touching the device and allow clenching and intense muscle contraction to occur. In such cases, tooth structure will actually be removed from the tip of these teeth.

The design of this new apparatus completely precludes this possibility, without the need for any adjustments to address this problem at future visits (which are time consuming and costly to the patient).

The requirement to remove tooth structure from healthy lower cuspid teeth is completely eliminated.

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any forward or lateral resistance to the lower part of the device and, because of the shape of the platform, the only force which can be applied to the lower anterior teeth is along the long axis of the teeth. Teeth can best resist forces exerted down their long axis - much more so than forces exerted in any other direction. This one aspect of the design greatly reduces the threat to the integrity of the periodontal health of the patient's teeth.

The invention, as exemplified by a preferred embodiment, is described with reference to the drawings in which:

Figure 1 is a view of both parts of the apparatus showing them in place on the teeth as seen from the front of the mouth showing also how the two parts come together and prevent the posterior teeth from coming into contact.

Figure 2 shows both parts of the apparatus on the teeth as seen from the lateral aspect, showing how the parts come together and prevent the posterior teeth from coming into contact.

Figure 3 is a plan view of the upper part of the apparatus in place on the teeth.

Figure 4 is a view of upper part of the apparatus shown in figure 3 shown from the front of the mouth.

Figure 5 is a cross-sectional view of the upper part of the apparatus in figures 3 and 4 taken through its midline.

Figure 6 is a plan view of the lower part of the apparatus in place on the teeth

Figure 7 is a view of the lower part of the apparatus shown from the front of the mouth

Figure 8 is a cross-sectional view of the lower part of the apparatus taken through its midline

Referring further to the drawings, figure 1 shows the upper part of the apparatus (10) and the lower part of the apparatus (11) and shows how they engage each other when the teeth come together. The dome of the lower part (12) engages the flat platform (13) of the upper part thus preventing the posterior teeth from coming into contact.

The extension of the flat platform of the upper part beyond the labial surfaces of the upper teeth (14) can be clearly seen, as can the extension up the labial surfaces (15)

The top surface of the lower part is clearly visible (16) as is its lower border (17). The main body

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of the lower part is extended laterally to include the four lower incisors but must be kept clear of the cuspids (18).

Figure 2 also shows how the two part of the apparatus come together with the dome of the lower (12) engaging the flat platform (13) of the upper. This drawing also shows that, due to the shape of the platform, and the position of the platform on the upper and the dome on the lower parts of the apparatus, no matter where the patient is able to position the mandible, the forces exerted by the muscles are always transmitted through the long axis of each of the four lower incisors.

In figure 3 which is a plan view of the upper part of the apparatus, the curved anterior border of the upper part is shown (19) having the same curvature as the arch of the teeth. The smooth, flat platform (13) can be seen showing the position and shape of its posterior border (20). The forward extension of the flat platform beyond the labial surface of the upper teeth (14) is much easier to see and understand in this view. This forward extension of the platform is extremely important to the success of the apparatus and is determined by the patients ability to protrude the mandible and is custom made to that criterion.

In figure 4 the curved anterior border of the upper part is shown (19) as is the extension of the flat platform beyond the labial surfaces of the teeth (14).

In figure 5, the posterior border of the upper part of the apparatus (20) is clearly indicated as is the smooth, flat platform (13). The significance of this platform can be seen in this view as it eliminates the irregularities presented by the shapes of the teeth which could provide resistance to the lower part of the apparatus hence allowing the forces exerted by the muscles to be directed against an individual tooth. The flat platform eliminates this possibility altogether. The extension of the platform beyond the labial surface of the teeth is shown (14) and its extension up the labial surface of the teeth is also indicated (15).

Figure 6 shows the anterior border of the lower device and its curvature to conform to the lower

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teeth (21). The top surface (16) is seen in plan view and the lateral extension of the apparatus (18) is shown to be quite clear of the cuspid teeth. The inner curved surface of the device is indicated (22). The integral plastic dome and its location on the top surface is shown (12). The exact positioning of this dome is very important in order that the forces exerted by the muscles are transmitted down through the long axis of the four lower incisors.

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Figure 7 shows the integral plastic dome (12) which engages the flat platform of the upper device. The upper surface of the device is seen (16) and the lateral extension being kept clear of the cuspid teeth is also shown (18) as is the lower border of the device (17).

Figure 8 shows the anterior border of the lower part (21), the dome (12), the upper surface (16), the inner curved surface (22) and the lower border (17).

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This apparatus, in its preferred embodiment, is constructed of methylmethacrylate, a plastic material used routinely in the construction of dentures. The material is cured to reduce absorption of mouth fluids and oral bacteria and to present a smooth non-irritating surface to the soft tissues of the mouth.

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The apparatus, in its preferred embodiment, is designed, formed in wax, flasked in a mold, the wax burned out and replaced in the mold by the methylmethacrylate, cured, finished and finally polished - all using the same techniques and processes used in the construction of dentures.

Although only a single embodiment of the present invention has been described and illustrated, the present invention is not limited to the features of this embodiment, but includes all variations and modifications within the scope of the claims.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY

OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

- 1. A custom, two piece, intra-oral apparatus which reduces muscle contraction, comprising:

 an upper part which fits over, and is closely adapted to, preferably, the maxillary front six teeth

 forming a smooth, flat platform whose anterior border follows the curvature of the teeth and

 extends beyond their labial surfaces to a distance slightly beyond that to which the patient is able

 to bring the dome of the lower part of the apparatus when fully protruding their mandible, with a

 posterior border running across the palate from cuspid to cuspid;
- a lower part which fits over, and is closely adapted to, usually, the lower four incisor teeth with a small

 dome located on its upper surface over the longitudinal axis of the two central incisors at the

 midline, in such a manner that when the upper and lower teeth are closed together, the dome

 engages the flat platform of the upper part of the apparatus thus preventing any contact of the

 posterior teeth, and causing the forces exerted by the elevator muscles of the mandible to be

 directed down through the long axes of the lower incisor teeth.
 - 2. An intra-oral apparatus as claimed in claim 1, wherein the actual number of maxillary teeth covered can vary, because that is not an essential element of the invention.
 - 3. An intra-oral apparatus as claimed in claims 1 and 2, wherein the anterior border of the upper part of the apparatus completely covers the labial surfaces of the maxillary teeth.
- 4. An intra-oral apparatus as claimed in claims 1, 2 and 3, wherein the shape and placement of the posterior border of the upper part of the apparatus can vary depending on the number of teeth incorporated in the apparatus.

- An intra-oral apparatus as claimed in claims 1, 2, 3 and 4, wherein the shape of the raised dome of the lower part of the apparatus is not defined because shape is not the essential element; it is the location and the fact that it is raised which are the essential elements.
- 6. An intra-oral apparatus as claimed in claims 1, 2, 3, 4 and 5, wherein the lower part of the apparatus has flanges extending laterally from the front and/or back surfaces, following the curvature of the arch of the teeth.
 - 7. An intra-oral apparatus as claimed in claims 1, 2, 3, 4, 5 and 6, wherein wire extensions extend laterally from either or both sides of the body of the lower part of the apparatus.
- 8. An intra-oral apparatus as claimed in claims 1, 2, 3, 4, 5, 6 and 7, wherein stainless steel wire or orthodontic wire clasps are added on either the upper or lower or both parts of the apparatus to aid in retention
 - 9. An intra-oral apparatus as claimed in claims 1, 2, 3, 4, 5, 6, 7, and 8 wherein a vinyl resin is used to construct the apparatus instead of methylmethacrylate.
- An intra-oral apparatus as claimed in claims 1, 2, 3, 4, 5, 6, 7 and 8, wherein a light cured resin is used to construct the apparatus instead of methylmethacrylate.
 - 11. An intra-oral apparatus as claimed in claims 1, 2, 3, 4, 5, 6, 7 and 8, wherein a silicone material is used to construct the apparatus instead of methylmethacrylate.
 - 12. An intra-oral apparatus as claimed in claims 1, 2, 3, 4, 5, 6, 7 and 8, wherein the material of construction of the apparatus is not an essential element.
- An intra-oral apparatus as claimed in claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12, wherein a soft lining material which is actually an integral part of the apparatus is placed between the apparatus and the teeth to act as a gasket to aid in retention.

- 14. An intra-oral apparatus as claimed in claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12, wherein the material of construction of the apparatus is a two part hard/soft acrylic material with the soft part on the inside (or fitting side) of the apparatus to aid in retention, surrounded on the outside by the hard acrylic.
- The method of reducing the intensity of muscle contraction of the elevator muscles of the mandible and hence the incidence of headache pain, by means of the construction and fitting of the custom, intra-oral apparatus described, to be worn by the patient while asleep, or at other times considered appropriate, but not to be worn while eating.

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FIG. I

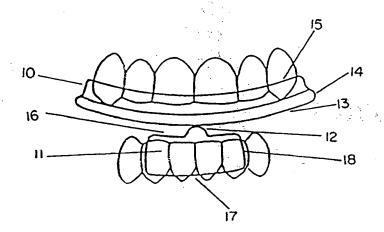
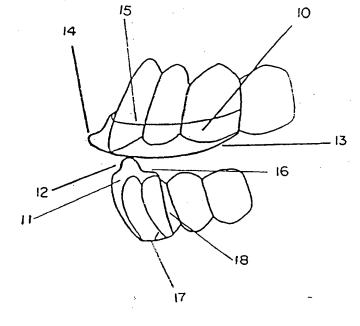
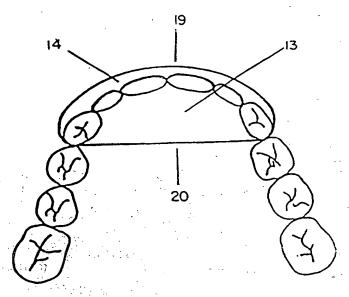


FIG. 2





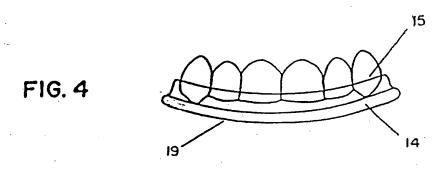
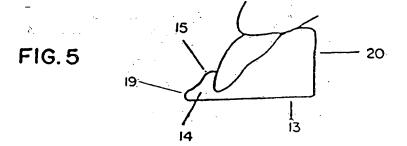


FIG. 3



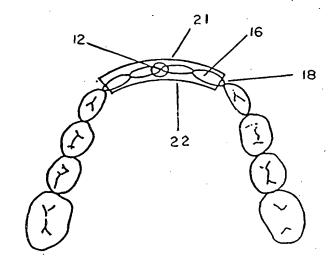
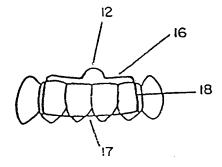


FIG. 7

FIG. 6



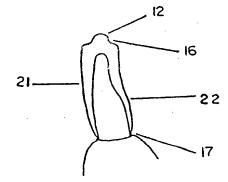


FIG.8